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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,883	10/06/2000	Bernard R. Brodeur	047998/0197	3090

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,883

Applicant(s)

BRODEUR, BERNARD R.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-124, 126-129, 131-137, 158-160, 163-174, 180-184 and 186-209 is/are pending in the application.
- 4a) Of the above claim(s) 91-123, 126, 131, 132, 158-160 and 163-169 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124, 133-137, 170-174, 180-184, 186-199, 204-206, 208 and 209 is/are rejected.
- 7) ☒ Claim(s) 127-129, 200-203 and 207 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicants amendment filed July 1, 2005 has been received and entered. Claims 1-90, 125, 130, 138-157, 161-162, 175-179, and 185 have been cancelled. New claims 197-209 have been added. Consequently, claims 91-124, 126-129, 131-137, 158-160, 163-174, 180-184, 186-209 are pending in the instant application, of which claims 91-123, 126, 131-132, 158-160, and 163-169 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claim 124 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "stringent conditions" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The rejection of claims 124, 133-137, 170-174, 180-184, and 186-196 under 35 U.S.C. 102(b) as being anticipated by Merks et al is maintained. Additionally, this rejection is applied to newly submitted claims 197-199, 204-206, and 208-209.

Applicants are asserting that Merks expressly refer to the disclosed protein as being only "partially purified." Applicants further assert that the one dimensional SDS-

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PAGE gels utilized in Merks to resolve the alleged 20 kDa protein would not have produced an isolated protein, nor a protein which is free of other *N. meningitidis* proteins. Applicants have submitted a publication by Bernardini et al (2004) which establishes that there are numerous proteins that migrate in the molecular weight range of about 20 kDa.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Merks expressly refer to the disclosed protein as being only "partially purified." However, Applicants are respectfully directed to claims 9-13 of Merks which claim an "isolated antigen" of 20 kDa.

Second, Applicants further assert that the one dimensional SDS-PAGE gels utilized in Merks to resolve the alleged 20 kDa protein would not have produced an isolated protein, nor a protein which is free of other *N. meningitidis* proteins. However, cancerweb.ncl.ac.uk defines the term "isolate" as "to separate from other persons, materials or objects." Consequently, even the band on the gel, with all proteins except those of 20 kDa removed, would meet the definition of "isolated." Furthermore, beyond the presence of the protein in the gel, Merks disclose of radioimmunoassay and ELISA's in which monoclonal antibodies bound the 20 kD protein. (See pages 15-16).

Finally, Applicants have submitted a publication by Bernardini et al (2004) which establishes that there are numerous proteins that migrate in the molecular weight range of about 20 kDa. However, as set forth above, Merks claim an "isolated" surface protein antigen from *Neisseria* with a molecular weight of about 20 kDa. This protein disclosed

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by Merks and the instantly claimed protein are both: surface proteins, obtained from Neisseria, have a molecular weight of about 20 kDa, are antigenic, and are stained by Coomassie blue. Accordingly, the disclosure of Merks is deemed to anticipate the instantly claimed protein.

Claim Rejections - 35 USC § 112

3. The rejection of claims 124-125, 127-129, 133-137, 170-196 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "an apparent molecular weight of 22 kDa" is withdrawn in view of Applicants amendment.

Claims 127-129, 200-203 and 207 are objected to for depending upon a rejected base claim, however claims 127-129, 200-203 and 207 are free of the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
September 7, 2005